

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC,

Plaintiff,

v.

HETERO USA, INC., HETERO LABS LTD., and  
HETERO LABS LTD. UNIT-VI,

Defendants.

C.A. No. 1:24-cv-01025-JLH

**DEFENDANTS HETERO USA, INC., HETERO LABS LTD., AND  
HETERO LABS LTD. UNIT-VI'S OPENING BRIEF IN SUPPORT OF THEIR MOTION  
FOR SUMMARY JUDGMENT**

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## **INTRODUCTION**

The Federal Circuit has made clear that “once the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under the principles of collateral estoppel.” *See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1379 (Fed. Cir. 1999) (quoting *Mendenhall v. Barber–Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994)). Because all claims of the sole patent asserted in this case have been held invalid by another court, Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI (collectively, “Hetero” or “Defendants”) are entitled to a judgment of invalidity as a matter of law.

## **BACKGROUND**

### **A. The ’952 Patent**

U.S. Patent No. 10,993,952 (“the ’952 patent”), titled “Stable ready to Use Cyclophosphamide Liquid Formulations,” was issued by the U.S. Patent and Trademark Office on May 4, 2021. *See* Statement of Facts (“SOF”) ¶ 1, D.I. 1-1. The patent contains four claims directed to formulations of cyclophosphamide, which all require a stable liquid parenteral formulation. SOF ¶ 1, D.I. 1-1 at Abstract (“The present invention relates to stable ready to use liquid formulations of Cyclophosphamide for parenteral use.”). Claim 1 of the ’952 patent, which is the only independent claim, requires in the preamble “[a] stable liquid parenteral formulation.” SOF ¶ 1, D.I. 1-1 at Claim 1. Claims 2-4 depend from claim 1 and therefore similarly require a stable liquid parenteral formulation. SOF ¶ 1, D.I. 1-1 at Claims 2-4.

### **B. The Northern District of Illinois Litigation**

Plaintiffs Ingenus Pharmaceuticals, LLC (“Ingenus”) and Leiutis Pharmaceuticals, LLP asserted infringement of the ’952 patent against Nexus Pharmaceuticals, Inc. on June 1, 2022 in the Northern District of Illinois. SOF ¶ 2, Exhibit 1, Complaint for Patent Infringement, *Ingenus*

*Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, No. 1:22-cv-02868 (N.D. Ill.), (D.I. 1). On December 6, 2024, Nexus moved for summary judgment on the grounds that all claims of the '952 patent were invalid as indefinite. SOF ¶ 3, Exhibit 2, Docket, *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, No. 1:22-cv-02868 (N.D. Ill.), D.I. 132-135 (Defendant's Motion for Summary Judgment – filed under seal)

After considering full briefing, including expert opinion as to the meaning of the disputed term, Judge Rowland issued a Memorandum Opinion and Order finding that all claims of the '952 patent were invalid. SOF ¶ 4, Exhibit 3, Memorandum Opinion and Order, *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, No. 1:22-cv-02868 (N.D. Ill.) (D.I. 215). In a well-reasoned and thorough eighteen-page opinion, the court explained that the term “stable”—which is used in all claims of the '952 patent—is indefinite as a matter of law:

[T]he '952 Patent has a term which could be ascertained by different measures, those measures could yield different results, and neither intrinsic nor extrinsic evidence indicates which to use. The term is thus indefinite.

*Id.* at p. 12. Based upon this finding, the Court entered final judgment of invalidity on May 9, 2025. SOF ¶ 6, Exhibit 4, Judgment in a Civil Case, *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, No. 1:22-cv-02868 (N.D. Ill.) (D.I. 216). Ingenus filed a Notice of Appeal on June 2, 2025. SOF ¶ 8, Exhibit 5, Notice of Appeal, *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, No. 1:22-cv-02868 (N.D. Ill.) (D.I. 219).

### **C. The Hetero Litigation**

Ingenus sued Hetero on September 11, 2024, in this Court, alleging that Hetero infringed a single patent—the same '952 patent Ingenus asserted in the Northern District of Illinois litigation. SOF ¶ 11, D.I. 1. Ingenus asserts that Hetero infringes all claims (claims 1-4) of the '952 patent. SOF ¶ 11, Exhibit 6, Plaintiffs' Paragraph 4(a) Disclosures.

In this litigation, Hetero asserts that the '952 patent is invalid because the term “stable” is indefinite.<sup>1</sup> SOF ¶ 12, Exhibit 7, Defendants’ First Supplemental Invalidity Contentions at pp. 45-47. Hetero’s indefiniteness argument is the same argument that the Northern District of Illinois adopted in its opinion holding the '952 patent invalid. SOF ¶ 13; *compare* Exhibit 7, Defendants’ First Supplemental Invalidity Contentions at pp. 45-57, Exhibit 3, Memorandum Opinion and Order at pp. 5-11.

## **ARGUMENT**

### **A. Legal Framework**

A defendant is entitled to summary judgment when a plaintiff “fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). “[A] mere ‘scintilla of evidence’ in the nonmovant’s favor does not create a genuine issue of fact.” *Ramara, Inc. v. Westfield Ins. Co.*, 814 F.3d 660, 666 (3d Cir. 2016). Rather, the plaintiff “must introduce evidence from which a rational finder of fact could find in [his or her] favor.” *Colburn v. Upper Darby Twp.*, 946 F.2d 1017, 1020 (3d Cir. 1991).

Collateral estoppel limits patent owners to “one full and fair opportunity for judicial resolution of the same [invalidity] issue.” *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 328 (1971). “[O]nce the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under principles of collateral estoppel.” *Pharmacia & Upjohn Co.*, 170 F.3d at 1379 (quoting *Mendenhall*, 26 F.3d 1577). The District of Delaware routinely applies collateral estoppel to patent claims held invalid by other courts. *See, e.g., Biogen Int’l GmbH v.*

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<sup>1</sup> Hetero has asserted other defenses in this litigation. This brief focuses only on the indefiniteness defense that is the basis for collateral estoppel.

*Amneal Pharms. LLC*, 487 F. Supp. 3d 254, 262-68 (D. Del. 2020); *Wireless Discovery LLC v. eHarmony, Inc.*, 654 F. Supp. 3d 360, 367 (D. Del. 2023); *IBM v. Rakuten, Inc.*, No. 21-cv-461, 2022 WL 17848779, D.I. 230 (D. Del. Dec. 22, 2022).

In addition, the “law is well settled that the pendency of an appeal has no effect on the finality or binding effect of a trial court’s holding.” *Pharmacia & Upjohn Co.*, 170 F.3d at 1381 (quoting *SSIH Equipment S.A. v. ITC*, 718 F.2d 365, 370 (Fed. Cir. 1983)); *see also Galderma Labs. Inc. v. Amneal Pharms., LLC*, 921 F. Supp. 2d 278, 281 (D. Del. 2012) (same); *PureWick Corp. v. Sage Prods., LLC*, No. 1:22-cv-102, 2023 WL 2734779, at \*11 (D. Del. Mar. 31, 2023) (same).

Collateral estoppel, also known as issue preclusion, “precludes parties from relitigating an issue that they previously had a full and fair opportunity to litigate.” *Rakuten, Inc.*, 2022 WL 17848779 at \*3. The doctrine applies when (1) “the identical issue was previously litigated” (2) “the issue was actually decided on the merits and the decision was final and valid”; (3) “the previous determination was necessary to the decision”; and (4) “the party being precluded from re-litigating the issue was adequately represented in the previous action.” *Galderma*, 921 F. Supp. 2d at 280.

## **B. Ingenus Is Collaterally Estopped From Asserting that the ’952 Patent Is Valid.**

### ***1. Hetero’s Indefiniteness Defense Is the Same as the Indefiniteness Defense Litigated in the Northern District of Illinois Action.***

The first step in the collateral estoppel analysis is to determine whether the issue to be precluded is the same as the issue previously decided. *Biogen Int’l GmbH*, 487 F. Supp. 3d at 262. “Identity of the issue is established by showing that the same general legal rules govern both cases and that the facts of both cases are indistinguishable as measured by those rules.” *Suppan v. Dadonna*, 203 F.3d 228, 233 (3d Cir. 2000) (quotation marks and citation omitted). In the context



of patent infringement, Federal Circuit law applies in determining whether the “identity of the issue” requirement of collateral estoppel is met. *Cf. Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1341 n.1 (Fed. Cir. 2012).

There is no dispute that the invalidity issue decided in the Northern District of Illinois is the same as the invalidity issue in this case. While “there is some question as to whether invalidity is a single issue or is divided into distinct issues based on the invalidity grounds,” the invalidity defense here is identical to the one presented in the Northern District of Illinois. *See Biogen Int’l GmbH*, 487 F. Supp. 3d at 263.

Thus, regardless of the level of analysis, the “identity of the issues” requirement is met here. Not only was the general issue of invalidity decided by the Northern District of Illinois, but that judgment concerns the same indefiniteness defense asserted by Hetero in this case against the same patent claims—claims 1-4 of the ’952 patent. SOF ¶¶ 11, 14-15. Both the Northern District of Illinois court’s ruling and Hetero’s invalidity position are based on the indefiniteness of the term “stable” and use the same reasoning. *Id.*, ¶¶ 14-15. As such, there is a complete unity of the issues in both cases, and the “identity of the issues” requirement of collateral estoppel is satisfied.

## ***2. The Indefiniteness Issue Was Decided on the Merits and Incorporated into a Final Judgment on the Merits.***

It is undisputed that the indefiniteness of the asserted claims of the ’952 patent was actually litigated and decided in the Northern District of Illinois action. *Id.*, ¶ 9. On December 6, 2024, Nexus moved for summary judgment on the grounds that all claims of the ’952 patent were invalid because the term “stable,” present in all claims, is indefinite. *Id.*, ¶ 3, Exhibit 2, Docket, D.I. 132-135 (Defendant’s Motion for Summary Judgment – filed under seal). On May 9, 2025, the court issued a Memorandum Opinion and Order finding that all claims of the ’952 patent were invalid. SOF ¶ 4; Exhibit 3, Memorandum Opinion and Order.

After considering full briefing and expert opinion as to the meaning of the term “stable,” the court issued a Memorandum Opinion and Order finding that all claims of the ’952 patent were indefinite. SOF ¶¶ 3-6, 9, Exhibit 3, Memorandum Opinion and Order. Based on that determination, the Northern District of Illinois entered final judgment of invalidity on May 9, 2025. SOF ¶ 6, Exhibit 4, Judgment in a Civil Case. The issue of the invalidity of the ’952 patent was thus determined by a final judgment in the Northern District of Illinois. SOF ¶ 6, Exhibit 4, Judgment in a Civil Case. This element is therefore met.

***3. The Indefiniteness Determination Was Necessary to the Northern District of Illinois Decision Invalidating the ’952 patent.***

The third element is whether the previous determination of invalidity was necessary to the judgment in the Northern District of Illinois case. *Biogen Int’l GmbH*, 487 F. Supp. 3d at 264. This element is met here because the indefiniteness determination was the basis for the Northern District of Illinois’s judgment invalidating the ’952 patent. SOF ¶ 7, Exhibit 3, Memorandum Opinion and Order. Thus, the same issue raised here by Hetero and previously decided in the Northern District of Illinois was necessary to the judgment in that case. *Biogen Int’l GmbH*, 487 F. Supp. 3d at 264.

***4. Ingenus Was Adequately Represented in the Northern District of Illinois Action.***

The final factor in the collateral estoppel analysis is whether Ingenus was fully represented in the Northern District of Illinois. As the Federal Circuit has explained, “a district court’s inquiry into whether the plaintiff was afforded a full and fair opportunity to litigate is quite narrow and does not involve a judgment on the merits.” *Pharmacia & Upjohn Co.*, 170 F.3d at 1380. Thus, this factor is “not focused on whether the prior invalidity determination was correct but rather on whether the patentee had a fair opportunity to litigate the issue.” *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 709 (Fed. Cir. 1983). “[T]he court is only to decide whether the patentee had

a full and fair opportunity to litigate the validity of [the] patent in the prior unsuccessful suit.” *Id.* at 709; *see also Biogen Int’l GmbH*, 487 F. Supp. 3d at 264-265.

In the Northern District of Illinois, Ingenus was represented by counsel, who fully briefed the issue of indefiniteness before that court. SOF ¶ 9, Exhibit 2, Docket, D.I. 132-135 (Defendant’s Motion for Summary Judgment – filed under seal), D.I. 153-156 (Plaintiffs’ Opposition – filed under seal), D.I. 175-178 (Defendant’s Reply – filed under seal) That is all that is required. Indeed, any argument that Ingenus was denied a fair opportunity to litigate “would be a hard sell as Defendant was represented by the same competent counsel” in both cases. *PureWick Corp.*, 2023 WL 2734779, at \*10; *see also Arunachalam v. Presidio Bank*, 801 F. App’x 750, 754 (Fed. Cir. 2020) (“Dr. Arunachalam was represented by counsel in the motions for summary judgment in JPMorgan. We find this proceeding to be a full and fair opportunity to litigate the issues.”).

Ingenus, however, apparently plans to make such an argument, suggesting in prior briefing that Judge Rowland in the Northern District of Illinois denied Ingenus a full and fair opportunity to litigate because she “did not hear evidence and did not hold oral argument.” D.I. 64 at 7. This argument is completely without merit. Rule 56 of the Federal Rules of Civil Procedure allows a court to “grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). That is precisely what the Northern District of Illinois did in granting summary judgment of invalidity after full briefing.

Ingenus, represented by the same counsel who represents them here, submitted an opposition brief where it had the opportunity to offer any evidence and arguments as to why summary judgment should be denied. Exhibit 2, Docket at D.I. 153-156 (Plaintiffs’ Opposition – filed under seal). Judge Rowland considered Ingenus’s arguments and rejected them, finding that

the claims of the '952 patent were indefinite as a matter of law in a well-reasoned and thorough eighteen-page opinion that considered opinions offered by both parties' experts. *See generally* Exhibit 3, Memorandum Opinion and Order. Like the district court in the *Pharmacia & Upjohn Co.* case, Judge Rowland "rendered a careful, methodical analysis" of the issue relevant to collateral estoppel. *Pharmacia & Upjohn Co.*, 170 F.3d at 1380. The summary judgment decision was "not preliminary in nature, but made clear that [the court had] fully and finally resolved the matters addressed" in a "fully reasoned opinion[.]" *See Dana v. E.S. Originals, Inc.*, 342 F.3d 1320, 1324 (Fed. Cir. 2003).

Thus, Ingenus was fully represented in the Northern District of Illinois and had a full and fair opportunity to litigate the issue of indefiniteness before that court. Any argument to the contrary is without merit.

#### ***5. No Other Factors Apply.***

Once the Court determines that the four elements of collateral estoppel are met here, Plaintiff is estopped from asserting that the sole patent in this case is valid. As a defendant cannot infringe an invalid patent, all that is left to do is enter judgment in favor of Hetero on Ingenus's infringement claim. *See Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) ("The claim being invalid there is nothing to be infringed."). The Court need not analyze any other factors.

As this Court has explained, the considerations of justice and equity are "not standalone considerations committed to the Court's discretion that can be used to avoid estoppel when the four requirements are otherwise satisfied." *Biogen Int'l GmbH*, 487 F. Supp. 3d at 266 (analyzing both Third Circuit and Federal Circuit law). And as Judge Noreika elaborated in *Biogen Int'l GmbH*, "the now-preclusive judgment of invalidity presents the very real prospect that this Court would never need to address any of the invalidity grounds raised by Defendants here." *Id.* at 268.

Thus, “[f]or the Court to undertake the effort to decide all the issues anew seems like an exercise in judicial inefficiency and disregard for a judgment that should be afforded preclusive effect.” *Id.* at 268.

Finally, Ingenus cannot argue that its appeal of the Northern District of Illinois decision prevents collateral estoppel from applying in this case. As the Federal Circuit has made clear, the pendency of an appeal has no effect on the finality or binding effect of a trial court’s holding. *Pharmacia & Upjohn Co.*, 170 F.3d at 1381; *see also PureWick Corp.*, 2023 WL 2734779, at \*11; *DietGoal Innovations LLC v. Chipotle Mexican Grill, Inc.*, 70 F. Supp. 3d 808, 816 (E.D. Tex. 2014) (Bryson, J. sitting by designation).

### **CONCLUSION**

For the foregoing reasons, collateral estoppel applies, and this Court should hold that the claims of the ’952 patent are invalid as a matter of law. Hetero respectfully requests that this Court grant its motion for summary judgment as a matter of law and enter final judgment of invalidity in favor of Hetero on Count 1 (alleged infringement of the ’952 patent), the sole count of Plaintiffs’ complaint, and on Count II of Hetero’s counterclaims (declaratory judgment of invalidity of the ’952 patent).

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